

REMARKS

Claims 1 and 83 have been amended. Claims 74, 75, and 96 have been canceled. Claims 1-13, 18-60, 64-73, and 79-94 are currently pending. Re-examination and reconsideration of the pending claims, as amended, is respectfully requested.

35 U.S.C. §103 - I

The Office Action rejects claims 1-13, 18-52, 54-75, 79-94, and 96 under 35 U.S.C. §103(a) as being unpatentable over Farley et al. (U.S. Patent No. 6,152,899) in combination with Burnside et al. (U.S. Patent No. 6,071,281) and Jackson et al. (U.S. Patent No. 5,846,238).

Generally, the present rejection does not establish *prima facie* obviousness under 35 U.S.C. §103 and M.P.E.P. §§2142-2143. The Examiner bears the initial burden to establish and support *prima facie* obviousness. *In re Rinehart*, 531 F.2d 1048, 189 U.S.P.Q. 143 (CCPA 1976). To establish *prima facie* obviousness, three basic criteria must be met. M.P.E.P. § 2142. First, the Examiner must establish that the prior art references, alone or in combination, teach or suggest all the claim limitations. M.P.E.P. §2143.03; *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). Second, the Examiner must show some suggestion or motivation, either in the prior art references or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the reference teachings so as to produce the claimed invention. M.P.E.P. § 2143.01; *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). Third, the Examiner must establish that there is a reasonable expectation of success for the modifications. M.P.E.P. § 2142. Applicant respectfully submits that a *prima facie* case of obviousness has not been met because the Examiner's rejection fails on at least two of the above requirements.

First, Applicant notes the cited art, alone or in combination, fails to teach or suggest all the claim limitations of amended independent claims 1 and 83. Independent claim 1 now reads, in part, that the deployment wire moves the radially expandable portion so as to permit deflection of the plurality of legs away from the deployment wire. Further, this claim requires that the same deployment wire provide current to the energy transfer elements, which when energized alter the bronchus or bronchiole wall so as to

treat asthma. Claim 83 has been similarly amended. These elements have not been shown or suggested by any of the patent references of record.

The Examiner asserts that “Jackson et al teach the use of a wire actuator, which alters the shape for the working element and also conducts energy to the working element.” Office Action, page 4. In particular,

With regard to Jackson et al, applicant argues that Jackson discloses the passage of the steering wire along with the signal wires, sighting column 12, lines 6-17. This argument fails for two reasons: firstly, in claim 59, for example, Jackson et al recite a device including ‘at least one wire having one end connected to the flexing element...ohmically heating body tissue by transmitting radio frequency energy through the electrode region...’ **such a method wherein the device includes exactly one wire, would require the bending wire to also be the current conducting wire;** secondly, the passage cited by applicant also includes the following ‘Further details of this and other types of steering mechanisms are shown in Lundquist and Thompson U.S. Pat. 5,254,088, which is incorporated into this Specification by reference.’ The referenced disclosure, bolstering the examiner’s interpretation of e.g. claim 59, states, in the paragraph bridging columns 13-14: ‘the steering wire is attached to the extreme distal end of a lead spring 1640 carried within a steering shaft 1650...The lead spring 1640 is held in place relative to the steering shaft 1650 by means of an adhesive 1670. The adhesive 1670 may include an electrically conductive material, if the steering shaft is to be utilized in an embodiment wherein an electrode is desired at the tip of the steering shaft.’, **which would clearly require the steering wire to be conductive, since the lead spring does not extend back to the proximal end of the device.**

Id., pages 2-3 (emphasis added).

Applicant respectfully disagrees. Jackson et al. fails to teach a deployment wire which moves the radially expandable portion so as to permit deflection of the plurality of legs away from the deployment wire, as required by the independent claims. The wire actuator in Jackson et al., namely the steering wires 60, in stark contrast, deflect the leaf spring 62, and hence the expandable body 22, in the direction of the pulled steering wire 60. Col. 13, lines 24-27; Figs. 12-13. In other words, actuation of any of the steering wires 60 does not deflect the expandable body 22 away from wire 60. Instead, the push-pull action of the stilette 76 is what deploys the expandable body 22. Col. 12, Section E. Push-Pull Stilette.

Further, Jackson et al. fails to teach or suggest that the same deployment wire provide a current to the energy transfer elements, which when energized alter the bronchus or bronchiole wall so as to treat asthma, as required by the independent claims. The electrode structures of Jackson et al., which are deployed in the heart for diagnosis and treatment of cardiac conditions, clearly teach separate energy signal wires 26 to provide current to the electrically conducting shell 24. As described in col. 21, lines 30-36:

it is necessary to electrically connect the shell 24 (or other ablation energy transmitting material 84) to the radio frequency energy generator 30 using the one or more signal wires 26. As before described, these signal wires 26, electrically connected to the shell 24, extend between the body 22 and the external connectors 28 through the catheter tube 12.

In col. 20, lines 7-10, Jackson et al. further states, “regardless of the orientation of the zones 122 (bull’s eye or circumferential), each energy transmission zone 122 is coupled to a dedicated signal wire 26 or a dedicated set of signal wires 26.” Further, in col. 12, lines 11-14, it is again noted that, “the wires 60 pass with the ablation energy signal wires 26 through the catheter tube 12 and connect to the left and right sides of a resilient bendable wire or leaf spring 62 adjacent the distal tube end 16 (see FIG. 12).” Also, the depiction in Fig. 1 illustrates separate steering and energy signal wires. Col. 21, Section IV. Electrical Connection to Shell.

Examiner’s citation of claim 59 in Jackson et al. as requiring the steering wire as also being the current conducting wire, is reproduced below:

59. A method for heating body tissue comprising the steps of
providing a catheter tube having a distal end that carries a collapsible electrode comprising a structure having an axis and a distal end, the structure comprising a wall peripherally enclosing an interior, the structure adapted to selectively assume an expanded geometry having a first maximum diameter about the axis and a collapsed geometry having a second maximum diameter about the axis less than the first maximum diameter, an electrically conductive material carried by the wall forming an electrode region adapted to conform to both the normally expanded geometry and the collapsed geometry of the structure, a flexing element in the interior of the structure connected to the distal end of the structure, the flexing element adapted for bending within the interior along the axis of the structure to displace the distal end relative to the axis, and **at least one wire having one end connected to the flexing element and an opposite end extending outside the interior for manipulation to remotely impart a bending force upon the flexing element,**
electrically coupling a source of radio frequency energy to the electrode region

and to a return electrode in contact with body tissue,
guiding the catheter tube into a body while causing the collapsible electrode to assume the collapsed geometry,
causing the collapsible electrode to assume the expanded geometry in association with body tissue,
manipulating the at least one wire to remotely impart a bending force upon the flexing element to displace the distal end of the structure relative to the axis, and
ohmically heating body tissue by transmitting radio frequency energy through the electrode region from the source to the return electrode.

(Emphasis added). This cited method claim falls far short of suggesting an all in one deployment and current conducting wire. Jackson et al. clearly describes the use of dedicated signal wires 26 throughout its disclosure to provide current to the electrically conducting shell 24. Omission of a signal wire element in an open ended method claim does not explicitly or implicitly suggest the steering wire be conductive. Likewise, even assuming that there was only exactly one steering wire connected to the flexing element, still does not explicitly or implicitly suggest the steering wire be conductive. Equally significant, the steering wire of Jackson et al. simply does not comprise a deployment wire that deflects the expandable body away from wire.

Examiner's additional reference to the Lundquist et al. patent is not relevant, as it is limited to describing alternative steering mechanisms 1470, 1480, which like the steering wires 60 of Jackson et al., do not teach or suggest a wire actuator that deflects the expandable body away from the wire. Figs. 21-22. In addition, disclosure that the adhesive 1670 may include an electrically conductive material in an embodiment wherein an electrode is desired at the tip of the steering shaft and/or the depiction of the lead spring not extending back to the proximal end of the device, as cited by Examiner, does not remotely provide any explicit or implicit inference that the steering wire in Lundquist et al. or Jackson et al. be conductive. Applicant notes that hindsight reconstruction is impermissible.

Secondly, Applicant notes that there is no motivation or suggestion, either in the cited art references or in the knowledge generally available to one of ordinary skill in the art, to combine the Jackson et al. and Farley et al. references so as to produce the claimed invention. The Examiner asserts that the to employ the wire configuration taught by Jackson et al. in the Farley et al. device "would impart a dual function to the actuating

member, thereby reducing the complexity and girth of the device, thus producing a device such as claimed.” Office Action, page 4. In particular,

it is further noted that the examiner’s specifically stated motivation can be found within Farley et al (‘899), at column 3: ‘reducing the number of wires can greatly reduce this concern’ (see lines 19-20) and ‘those skilled in the art have recognized the needs for an expandable electrode catheter that has increased electrode size while maintaining the catheter size as small as practical.

Id., page 2.

It is Applicant’s position that these cited sections fail to provide the requisite motivation needed for one of skill in the art to replace the slidable outer tube 52, which expands the electrodes 22 in Farley et al., with the claimed deployment wire that moves the radially expandable portion so as to permit deflection of the plurality of legs away from the deployment wire and provides a current to the energy transfer elements which when energized alter the bronchus or bronchiole wall so as to treat asthma. Applicant notes that hindsight reconstruction is impermissible. As the Examiner is certainly aware, the teachings or suggestions must be found in the prior art, rather than in Applicant’s disclosure. *In re Vaeck*, 947 F.2d 448, 20 U.S.P.Q.2d 1438 (CAFC 1991).

Applicant further points out that the Examiner bears the initial burden of factually establishing and supporting any *prima facie* conclusion of obviousness. *In re Rinehart*, 531 F.2d 1048, 189 U.S.P.Q. 143 (CCPA 1976); M.P.E.P. § 2142. If the Examiner does not produce a *prima facie* case, the Applicant is under no obligation to submit evidence of nonobviousness. *Id.* In the instant case, the Examiner has not pointed to any concrete evidence in the art which provides a suggestion or motivation to combine the Farley et al. and Jackson et al. patents so as to produce the claimed invention of claims 1 and 83. See *In re Zurko*, 258 F.3d 1379, 59 U.S.P.Q.2d 1693 (Fed. Cir. 2001) ([I]n a determination of patentability the Board cannot simply reach conclusions based on its understanding or experience - or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings).

For the several reasons discussed above, it is respectfully requested that the § 103(a) rejection of independent claims 1 and 83 (and the claims which depend therefrom) be withdrawn and the claims be allowed.

35 U.S.C. §103 - II

The Office Action rejects claim 53 under 35 U.S.C. §103(a) as being unpatentable over Farley et al. in combination with Burnside et al. and Jackson, as applied above, and further in combination with Fischell et al.

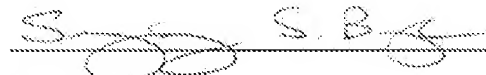
As noted above, the Office Action fails to establish a proper *prima facie* case. The addition of Fischell et al. does nothing to remedy this defect. In view of the above, Applicant requests withdrawal of this rejection.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **ASTXNA00300**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



Sanjay S. Bagade
Registration No. 42,280

Customer No. 40518
Levine Bagade Han LLP
2483 East Bayshore Road, Suite 100
Palo Alto, CA 94303
Direct: (650) 242-4212
Fax: (650) 284-2180